



Heads Up

Issue: 137

Date: 2008/12/03

To: ANAB Applicant and Accredited CBs and Accreditation Assessors

From: Randy Dougherty, Vice President, ANAB


Re: Improved Corrective Action Responses

The ANAB process for CBs to respond to nonconformances involves several steps, including correction, root cause analysis, corrective action, evidence of implementation, and verification of effective implementation.

Experience has shown that some responses are often less than adequate and in some cases these responses were accepted by ANAB accreditation assessors. Therefore, ANAB has developed a guidance tool for our assessors to use when reviewing corrective action responses from CBs.

This tool is nothing more than what CBs should have been providing as responses and what accreditation assessors should have been looking for in the corrective action responses from CBs. The information provided in the guidance tool is basic items that should be included in all corrective action responses.

ANAB will update EQM to include this guidance. In the meantime, please find the guidance attached and use it when responding to ANAB-issued NCRs.

ANAB ACCREDITATION ASSESSOR'S GUIDANCE FOR CORRECTIVE ACTION REVIEW		
<u>AUTHORITY:</u> ACCREDITATION MANAGER	<u>EFFECTIVE DATE:</u> 24 JUNE 2008	<u>DOCUMENT NUMBER:</u> FM 3007.00

Overall

NCR responses should be reviewed in three parts; correction, root cause analysis and corrective actions. These three parts are linked as outlined below.

In reviewing the three parts, ANAB looks for a plan and then evidence that plan is being implemented. In some cases, the CB may take action and not provide a plan; this is acceptable as long as the following guidance is met.

Overall guidance; keep in mind the original NCR statement and the requirement(s) that was referenced. Those must be addressed throughout the responses.

Correction – *in order to be fully accepted, the response must include the following components:*

1. The extent of the nonconformity has been determined and contained
 - a. The nonconformity has been corrected and the response is written in the past tense. (E.g. the missing record was found (not will be found)).
 - b. The CB has examined the system to see if there are other examples that need corrected (extent of the issue) and have also addressed the extent in their response.
 - c. Including the evidence ANAB found and any other evidence the CB may have found.
2. If correction can not be immediate; a plan to correct the NCR may be appropriate and shall include:
 - a. Identification of responsible parties for the actions and
 - b. a schedule (dates) for implementation
3. If applicable; all parties involved have been informed of the problem (identify internally affected parties, auditors, customers, etc).
4. Evidence that the correction was implemented or evidence that the plan is being implemented.

Root Cause Analysis – *in order to be fully accepted, the response must follow the following guidance:*

5. The Root Cause refrains from simply repeating the finding or the direct cause.
6. The Root Cause is a brief expression of fact that attempts to neither explain the situation away nor rationalize the condition.
7. A well thought out Direct Cause has been determined along with a well thought out analysis to determine the true root cause. (e.g. someone did not follow a process would be direct cause; determining why someone did not follow a process would lead to the true root cause)
8. The root cause statement must focus on a single issue.
 - a. If more than one cause is identified, for instance training and inadequate work instructions, then two Corrective Action plans must be submitted.
9. The Root Cause statement addresses a fundamental issue without any obvious “why” questions remaining.

- a. If a “why” question can reasonably be asked about the root cause analysis, this indicates that the analysis did not go far enough.
-

Corrective Action – *in order to be fully accepted, the response must include the following components:*

10. The corrective action or corrective action plan addresses the root cause(s) determined in the root cause analysis.
11. In order to accept the plan it shall include;
 - a. actions to address the root cause(s)
 - b. Identification of responsible parties for the actions and
 - c. a schedule (dates) for implementation.
12. In order to accept the evidence of implementation:
 - a. Enough evidence is provided to show the plan is being implemented as outlined in the response (and on schedule).
 - b. Note; Evidence in full is not required to close the NCR; some evidence may be reviewed during future assessment when verifying the corrective actions.